

### **Abstract**

This invention discloses a novel stable crystal form of imatinib mesylate, designated by us as  $\alpha_2$  Form, which is stable at room temperature and even at higher temperatures upto 120 °C and accelerated stress conditions and, freely soluble in water. This invention also discloses a pharmaceutical composition containing the novel stable  $\alpha_2$  form of Imatinib mesylate and other usually employed excipients, useful in the treatment of Chronic Myelogenous Leukemia (CML). This new  $\alpha_2$  Form of imatinib mesylate is prepared by slurring Imatinib base in isopropanol at room temperature followed by addition of methane sulfonic acid and maintaining 50-60 °C followed by filtration. This invention also discloses another process for the preparation of the novel, stable  $\alpha_2$  crystalline form of Imatinib Mesylate by the conversion of Imatinib mesylate  $\beta$ -polymorphic modification by suspending it in water and organic solvents, distilling off water azeotropically, cooling and filtering to obtain the  $\alpha_2$  crystal form.